

REMARKS

Claims 1-5, 7-16, 20, 21, and 26-29 are pending. Claim 26 has been withdrawn from consideration. Claims 6, 17-19, and 22-25 have been cancelled without prejudice or disclaimer of subject matter. Claims 27, 28 and 29 have been newly added. Claims 1, 15 and 16 have been amended to further define Applicants' invention, and Claims 20 and 21 have been amended to change their dependencies. Claims 1, 15, 14 and 26 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Rejections Under 35 USC §103

Claims 1-3, 5-9, 11-13, 15, 17-19 and 21-24 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,432,441 (*Bealin-Kelly et al.*) in view of U.S. Patent No. 5,578,316 (*Bhardwaj et al.*) and U.S. Patent No. 4,260,596 (*Mackles*). Claims 1-25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over EP Patent No. 0950402A2 (*Buehler et al.*) in view of U.S. Patent No. 6,060,078 (*Lee*), U.S. Patent No. 5, 578,316 (*Bhardwaj et al.*), U.S. Patent No. 4,753,790 (*Silva*), and U.S. Patent No. 4,260,596 (*Mackles*). Claims 1-25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,060,078 (*Lee*), in view of U.S. Patent No. 5, 578,316 (*Bhardwaj et al.*), U.S. Patent No. 4,753,790 (*Silva*), and U.S. Patent No. 4,260,596 (*Mackles*). Applicants respectfully traverse these rejections, in view of the comments set forth below.

One noteworthy feature of the texture masking dosage form recited in Claim 1 is a soft panned brittle shell encasing a molded soft core.

The dosage form of the present invention is designed to mask the grittiness of active agent particles contained therein. This is accomplished by encasing the molded soft core with the soft panned brittle shell.

Bealin-Kelly et al., is directed to a throat drop that has an edible shell and an aqueous filling, which may be in the form of a liquid, gel or paste. The filling includes a throat relief agent, water, and a vesicle-forming agent, which encapsulates the throat relief agents. *Bealin-Kelly et al.* does not does not disclose a molded soft core that is encased by a soft panned brittle shell. Furthermore, *Bealin-Kelly et al.* does not suggest nor contemplate that the throat relief agent (i.e., active agent particles) has a gritty texture such that some form of texture masking would be desirable.

Bhardwaj et al. is cited for disclosing a palatable chewable tablet that includes drug particles having a particle size from about 180 to 420 microns.

Mackles discloses a dosage form where a shell cavity is formed and then the cavity is filled with a liquid or gel center.

Neither *Bhardwaj et al.* nor *Mackles* remedy the deficiencies of *Bealin-Kelly et al.* That is, *Bhardwaj et al.* and *Mackles* do not teach or suggest a molded soft core that is encased by a soft panned brittle shell. In addition, like *Bealin-Kelly et al.*, *Bhardwaj et al.* and *Mackles* do not suggest or disclose the need to provide a texture masking feature to mask the grittiness of active agent particles contained therein.

As such, Claim 1 is patentable over *Bealin-Kelly et al.*, *Bhardwaj et al.* and *Mackles*, whether considered separately or in any proposed combination.

Independent Claims 15 and 16 are similar to independent Claim 1, except that Claim 15 identifies the active agent particles as acetaminophen and Claim

16 identifies the active agent particles as ibuprofen. For the same reasons as Claim 1, Claims 15 and 16 are patentable over *Bealin-Kelly et al.*, *Bhardwaj et al.* and *Mackles*, whether considered separately or in any proposed combination.

The remaining claims directly or indirectly depend from Claims 1, 15 or 16. Therefore, each of the remaining claims is also patentable over *Bealin-Kelly et al.*, *Bhardwaj et al.* and *Mackles*, whether considered separately or in any proposed combination for the reasons stated above.

Buehler et al. discloses a chewable composition comprising a gelatin matrix which contains a pharmaceutically active ingredient, a hydrocolloid, and water. However, unlike Claim 1 of the present invention, *Buehler et al.*, does not disclose that the gelatin matrix is encased in a soft panned brittle shell.

Lee is directed to a chewable pharmaceutical tablet containing a medicament in a core with an outer layer. The core may be in the form of a jelly and the outer layer may be a hard candy.

Silva et al. discloses a sorbitol coated comestible, with a substantially anhydrous core surrounded by a hard crunchy shell.

Bhardwaj et al. and *Mackles* have been discussed previously.

Applicants review of *Lee*, *Silva et al.*, *Bhardwaj et al.* and *Mackles* has not found any of those references to disclose or suggest a soft panned brittle shell encasing a molded soft core, as recited in Claim 1. Thus, *Lee*, *Silva et al.*, *Bhardwaj et al.* and *Mackles* do not remedy the deficiencies of *Buehler et al.* As such, Claim 1 is patentable over *Buehler et al.*, *Lee*, *Silva et al.*, *Bhardwaj et al.* and *Mackles*, whether considered separately or in any proposed combination.

Moreover, Claim 1 is also patentable over the proposed combination of *Lee, Silva et al., Bhardwaj et al.* and *Mackles*. As discussed above, none of these references disclose or suggest a soft panned brittle shell encasing a molded soft core, as recited in Claim 1.

Claims 15 and 16 are directed to compositions that are similar to the composition of Claim 1 in many respects, except that Claim 15 is directed to a texture masking oral dosage form where the active agent particles are acetaminophen, and Claim 16 is directed to a texture masking oral dosage form where the active agent particles are ibuprofen. Accordingly, for at least the same reasons discussed above for Claim 1, Claims 15 and 16 are patentable over the proposed combination of *Buehler et al., Lee, Silva et al., Bhardwaj et al.* and *Mackles*, or the proposed combination of *Lee, Bhardwaj, Silva, and Mackles*.

The remaining claims directly or indirectly depend from Claims 1, 15 or 16. Therefore, each of the remaining claims is also patentable over the proposed combination of *Buehler et al., Lee, Silva et al., Bhardwaj et al.* and *Mackles*, or the proposed combination of *Lee, Bhardwaj, Silva, and Mackles* for the reasons stated above.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time the claimed invention was made in light of the references cited. Thus, Applicants respectfully request that this rejection under 35 USC §103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and

an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP0281USNP/VT.

Respectfully submitted,

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